

Application No.: 10/528,742
Amtd. Dated: June 7, 2007
Reply to Office Action Dated: February 7, 2007

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REMARKS

Claims 1-15 are pending in the present application. Claims 1, 8, 9, and 13 have been amended. Support for the amended claims can be found throughout the specification and claims as originally filed. No new matter enters by way of this amendment.

Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

I. Introductory Comments

Prior to addressing the rejections of record, a brief description of the disclosure is provided for the convenience of the Examiner. The disclosure provides a wound treatment device comprising a water-impermeable envelope having at least one aperture. The envelope contains a therapeutic agent, and the at least one aperture is blocked by a degradable material that breaks down in the presence of one or more components of wound fluid, thereby permitting the therapeutic agent to contact the wound fluid. The envelope is a "small package or enclosure that can be inserted onto or into a wound," such that "[t]he device can be used in conjunction with a wide range of existing wound dressings, and is sufficiently small that it will not interfere with the absorbency of such dressings." *Specification* at page 3 lines 14-26. As the specification discusses, the "[t]ypical envelope configuration is a sachet formed by bonding together two sheets of film material (or one sheet folded over) around a periphery." *Specification* at page 4, lines 9-11.

II. Objections to the Specification and Claims

The Examiner has apparently objected to the specification for allegedly failing to use "proper format for an abstract of the disclosure." *Office Action* at page 2. Although the Examiner quotes multiple passages from the MPEP, no specific error in the abstract's format has been identified. However, in view of the amended abstract provided, any objection should be moot.

In addition, the Examiner has objected to claim 13 for typographical errors, and to claims 8-10 and 12 for informalities. *Id.* In view of the amendments to the claims, the objections are moot, and Applicants respectfully request reconsideration and withdrawal of the objections to the specification and claims.

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III. Claim Rejections under 35 U.S.C. § 102(e)

Claims 1-3 and 5-15 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Kirkwood et al., U.S. Application Publication No. 2004/0241214 (hereinafter "Kirkwood *et al.*"), which, as the Examiner notes, has common inventors with the present application. *Office Action* at pages 3-4. Applicants respectfully traverse for at least the following reasons.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 1 is directed to a wound treatment device comprising a water-impermeable envelope having at least one aperture, where the envelope contains a therapeutic agent, and where the at least one aperture in the envelope is blocked by a degradable material that breaks down in the presence of one or more components of wound fluid thereby permitting the therapeutic agent to contact the wound fluid. The cited reference does not disclose all of the features of the currently claimed invention. For example, Kirkwood et al. does not disclose or suggest a wound treatment device as claimed in claim 1, where the device comprises a water-impermeable envelope. As discussed in the instant specification, the envelope is a "small package or enclosure that can be inserted onto or into a wound," such that "[t]he device can be used in conjunction with a wide range of existing wound dressings, and is sufficiently small that it will not interfere with the absorbency of such dressings." The Examiner has not shown that Kirkwood discloses such a device.

Accordingly, Kirkwood et al. has not been shown to disclose all of the features of independent claim 1. Since the cited reference does not anticipate claim 1, neither does it anticipate dependent claims 2-15. As such, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e).

IV. Claim Rejections under 35 U.S.C. § 103

A. Rejection of Claim 4

Claim 4 has been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kirkwood et al. (U.S. Patent Application No. 2004/0241214). *Office Action* at page 5. Applicants respectfully traverse for at least the following reasons.

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To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. Moreover, there must be a reasonable expectation of success. A teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As discussed above, amended claim 1 is directed to a wound treatment device comprising a water-impermeable envelope having at least one aperture, where the envelope contains a therapeutic agent, and where the at least one aperture in the envelope is blocked by a degradable material that breaks down in the presence of one or more components of wound fluid thereby permitting the therapeutic agent to contact the wound fluid. The Kirkwood et al. reference does not disclose all of the features of the currently claimed invention. For example, Kirkwood et al. does not disclose or suggest a wound treatment device as claimed in claim 1, where the device comprises a water-impermeable envelope. As discussed in the instant specification, the envelope is a "small package or enclosure that can be inserted onto or into a wound," such that "[t]he device can be used in conjunction with a wide range of existing wound dressings, and is sufficiently small that it will not interfere with the absorbency of such dressings." The Examiner has not shown that Kirkwood discloses such a device.

With respect to claim 4, the Examiner acknowledges that "Kirkwood et al. fails to disclose the envelope having only one aperture." *Office Action* at page 5. The Examiner argues however that "the use of only one aperture by applicant serves no critical function, and solves no stated problem." *Id.* The Examiner then concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to use only one aperture..., since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art." *Id.*

The reference relied on by the Examiner, Kirkwood et al., discloses "a wound dressing comprising: a wound contacting sheet having a wound facing surface and a back surface opposite the wound facing surface, and having apertures there that open or enlarge in the presence of wound exudate; and a plurality of particles comprising one or more therapeutic agents located behind the back surface of the back sheet, wherein the particles are

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able to pass through the apertures to the wound facing surface of the sheet when the apertures are opened or enlarged in the presence of wound exudate." Kirkwood et al. at para. [0011].

In contrast, as discussed above, the device discussed in the instant specification, the envelope is a "small package or enclosure that can be inserted onto or into a wound," such that "[t]he device can be used in conjunction with a wide range of existing wound dressings, and is sufficiently small that it will not interfere with the absorbency of such dressings."

The Examiner has provided no support that the disclosure of Kirkwood et al. would have led one of ordinary skill in the art to modify the teachings therein to obtain the subject matter defined in the current claims. As claim 1 has not been shown to be obvious over Kirkwood, claim 4 likewise has not been established as obvious. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 4 under 35 U.S.C. § 103(a).

B. Rejection of Claims 1-15

Claims 1-15 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Arnold (U.S. Patent No. 5,759,570) in view of Burton (U.S. Patent No. 6,903,243). *Office Action* at page 5. Applicants respectfully traverse for at least the following reasons.

As set forth above, to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. Moreover, there must be a reasonable expectation of success. A teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner attempts to support the rejection by arguing that "it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Arnold device with the apertured layer over the degradable layer, as taught by Burton, in order to force the exudates towards the absorbent later and not allow a build up of exudates that may cause the wound dressing to fall off the skin." *Office Action* at page 6.

The Examiner has not shown that the combined references disclose or suggest all of the features of the currently claimed invention. For example, the Examiner has not shown that the combined references disclose or suggest device having the recited envelope having at least one aperture in the aperture that is blocked by a degradable material. The Examiner

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argues that "[t]he layer containing the therapeutic substance, dispersed on the wound contact layer, is degradable or bioabsorbable and contains collagen and glycosaminoglycans, which also provides a substrate for the enzymes to act upon." *Office Action* at pages 5-6. However, nothing that the Examiner points to indicates that recited layer blocks the pores in the molecular filtration layer of Arnold. Nor do the references disclose or suggest a water-impermeable envelope as recited. As such, the Examiner has not shown that the combination of references discloses all of the recited features.

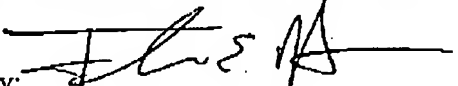
The Examiner has pointed to nothing in any of the cited references that would have led one of ordinary skill in the art to combine or modify the teachings therein to obtain the subject matter defined in the rejected claims. In view of the foregoing, a *prima facie* case has not been made. There is no motivation to combine and/or modify Arnold et al. in the manner alleged, and even if the combinations were made, the result would not be a wound treatment device as currently claimed. Thus, Applicants respectfully request that the rejections of claims 1-15 under 35 U.S.C. § 103(a) be withdrawn.

For the foregoing reasons, claims 1-15 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

HUTCHISON LAW GROUP PLLC

Date: June 7, 2007

By: 

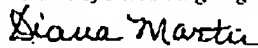
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Diana Martin

(Typed Name of Person Signing Certificate)



(Signature of Person Signing Certificate)